REMARKS

The amendments and remarks, as presented here, are believed to place the case in condition for allowance. Accordingly, entry of these amendments and allowance is respectfully requested. With this response claims 1-68 are pending herein.

Amendments to the Specification

Amendment of the paragraph beginning on page 4, line 7 is requested to replace the recitation "The first-level alarm pauses fluid flow in at least a portion of the system" with the recitation "In one embodiment, the first alarm condition comprises pausing the fluid flow in at least a portion of the system for a specific delay time. In an exemplary embodiment, the first alarm condition comprises pausing the fluid flow in at least a portion of the system for a delay time of about 2 seconds to about 6 seconds." The requested amendment merely incorporates the subject matter of claims 1 and 4, as original filed, into the specification and, thus, does not introduce any new matter.

Amendment of the paragraph beginning on page 5, line 24 is requested to replace the recitation "inlet pump hematocrit, ratio of anticoagulant to whole blood in an inlet line of the system during platelet and plasma collection, inlet pump flow rate, and donor hematocrit," with the recitation "a configuration specified system pressure, the flow rate in the inlet tubing line, the hematocrit in the inlet tubing line, the flow rate in the needle and the hematocrit in the needle". The requested change amends this paragraph to make specific reference to parameters useful for calculating a sensor pressure for triggering an alarm condition, which are set forth on page 26, lines 12 to 25 and on page 27, lines 1 - 14. The requested amendment does not introduce any new matter.

Amendments of the paragraph beginning on page 6, line 1 and the paragraph beginning on page 29, line 8 are requested to change the recitation:

> $P_{AAL} = P_{AALS} + 75 - 0.331\ Q_{ININSTD} / (1\text{-}H_{IN}) - 0.303\ Q_{ININSTD}\ (1 - 1/R) / (1 - H) = -350$ where P_{AAL} is the specified sensor pressure that triggers the first-level alarm; P_{AALS} is the specified first-level alarm-triggering system pressure, mmHg; H_{IN} is inlet pump hematocrit, decimal; $Q_{ININSTD}$ is instantaneous inlet pump flow rate (during the draw phase), ml/min; and R is ratio of whole blood to anticoagulant in an inlet line of said system during platelet and plasma collection.

to recite:

> specified sensor pressure = Config + 75 - 0.3309 * $Q_{in}/(1\text{-}H_{in})$ - 0.3026 * $Q_n/(1\text{-}H_n)$; where Config is a configuration specified system pressure (mmHg.), Q_{in} is the flow rate in the inlet tubing line (ml/min.); H_{in} is the Hematocrit in the inlet tubing line; Q_n is the flow rate in the needle (ml/min.); and H_n is the Hematocrit in the needle.

The requested amendments conform the description of exemplary methods for determining sensor pressures for triggering alarm conditions to be consistent with the description of exemplary embodiments beginning on page 26, line 12 and ending on page 27, line 14 and the description provided in parent application USSN 09/746,987. The requested amendments improve clarity and do not introduce new matter.

Amendment of the paragraph beginning on page 6, line 1 is also requested to insert the following recitation at the end of the paragraph:

> Alternatively, the sensor pressure which triggers the first-level alarm may be calculated using the formula: specified sensor pressure = Config + 75 - 0.3309 * $Q_{in}/(1\text{-}H_{in})$ - 0.5602 * $Q_n/(1\text{-}H_n)$; where Config is a configuration specified system pressure (mmHg.), Q_{in} is the flow rate in the inlet tubing line (ml/min.); H_{in} is the Hematocrit in the inlet tubing line; Q_n is the flow rate in the needle (ml/min.); and H_n is the Hematocrit in the needle.

The requested amendment is supported by the description of exemplary methods for determining sensor pressures for triggering alarm conditions provided on page 27 lines 15 to 23. The requested amendment does not introduce new matter.

Deletion of the entire paragraph beginning on page 6, line 18 and ending on page 6, line 22 is requested. The requested amendment improves overall clarity and does not introduce any new matter.

Amendment of the paragraph beginning on page 6, line 28 and ending on page 7, line 17 is respectfully requested to replace the recitation "return pump flow, return pump hematocrit, return needle flow rate, and return needle hematocrit," with the recitation "a configuration specified system pressure, the flow rate in the inlet tubing line, the hematocrit in the inlet tubing line, the flow rate in the needle and the hematocrit in the needle". The requested change amends this paragraph to make specific reference to parameters useful for calculating a sensor pressure for triggering an alarm condition, which are set forth on page 27, lines 24-27 and on page 28, lines 1-11. The requested amendment does not introduce any new matter.

Amendments of the paragraph beginning on page 6, line 28 and the paragraph beginning on page 31, line 13 is also requested to change the recitation:

> $P_{RAL} = P_{RALS} - 50 - 0.3331\ Q_{ININSTR} / (1 - H_{IN}) - 0.303\ Q_{NRET} / (1 - H_{NRET}) = 400$ where P_{RAL} is the sensor pressure that triggers the return-pressure alarm, mmHg; P_{RALS} is the specified system return-flow alarm-triggering pressure, mmHg, $Q_{ININSTR}$ is return pump flow, ml/min; H_{IN} is return pump hematocrit, decimal; Q_{NRET} is the flow rate through the needle during the single needle return phase, ml/min; and H_{NRET} is the hematocrit of the flow through the return needle.

to recite:

> specified sensor pressure = Config - 50 - 0.3309 * $Q_{in}/(1-H_{in})$ - 0.3026 * $Q_n/(1-H_n)$; where Config is a configuration specified system pressure (mmHg), Q_{in} is the flow rate in the inlet tubing line (ml/min.); H_{in} is the Hematocrit in the inlet tubing line; Q_n is the flow rate in the needle (ml/min.); and H_n is the Hematocrit in the needle.

The requested amendments conform the description of exemplary methods for determining sensor pressures for triggering alarm conditions to be consistent with the description of exemplary embodiments beginning on page 27, line 24 and ending on

page 28, line 11 and the description provided in parent application USSN 09/746,987. The requested amendments do not introduce new matter.

Amendment of the paragraph beginning on page 6, line 28 is also requested to insert the following recitation at the end of the paragraph:

> Alternatively, the sensor pressure for triggering the return-flow alarm condition is calculated using the formula: specified sensor pressure = Config - 50 - 0.3309 * $Q_{in}/(1-H_{in})$ - 0.5602 * $Q_n/(1-H_n)$;where Config is a configuration specified system pressure (mmHg), Q_{in} is the flow rate in the inlet tubing line (ml/min.); H_{in} is the Hematocrit in the inlet tubing line; Q_n is the flow rate in the needle (ml/min.); and H_n is the Hematocrit in the needle.

The requested amendment is supported by the description of exemplary methods for determining sensor pressures for triggering alarm conditions provided on page 28 lines 1 to 11. The requested amendment does not introduce new matter.

Amendment of page 9 is requested to include the following new paragraph on a new line after the recitation "apheresis system":

> In one embodiment the present invention provides a method for controlling a fluid separation system comprising the steps of: (1) triggering a first-level alarm condition in response to a pressure drop to less than or equal to a specified system pressure, said first alarm condition comprising pausing fluid flow in at least a portion of said system for a specified delay time; and (2) triggering a second alarm condition in response to a specified number of said pressure drops within a specified period, said second alarm condition comprising reducing flow rate of fluid in said system. Optionally, this method the present invention may further comprise the step of triggering a third alarm condition in response to failure of pressure in the system to rise to a specified first-level alarm-disabling pressure in the system. In another embodiment, the present invention comprises a method for controlling an apheresis system comprising the steps of: (1) triggering a first alarm condition in response to a specified pressure drop to less than or equal to a specified pressure in the system, said first alarm condition comprising pausing fluid flow in at least a portion of said system for a specified delay time; (2) if plasma and platelet collection is incomplete, triggering a second-level alarm condition in response to a specified number of said specified pressure drops within a specified period, said second alarm condition comprising reducing flow rate of fluid in said system; and (3) if plasma and platelet collection

> is complete, triggering a third-level alarm condition in response to a selected number of said selected pressure drops within a specified period, said third-level alarm condition comprising stopping all pumps. In yet another embodiment, the present invention provides a method for controlling flow rate of return of fluid to a fluid source in a fluid separation process wherein components have been separated from said fluid, said method comprising the step of specifying a system return-flow alarm-triggering pressure, and when pressure of said return flow in the system is higher than or equal to said specified pressure, triggering a return-flow alarm.

The requested amendment merely incorporates the subject matter of claims 1, 13, 27 and 28, as original filed, into the specification and, thus, does not introduce any new matter.

Amendment of the paragraph beginning on page 29, line 8 is also requested to replace the recitation "instantaneous inlet pump flow during the draw phase, inlet pump hematocrit, anticoagulant (AC) ratio during platelet and plasma collection, and donor hematocrit" with the recitation "a configuration specified system pressure, the flow rate in the inlet tubing line, the hematocrit in the inlet tubing line, the flow rate in the needle and the hematocrit in the needle." The requested change amends this paragraph to make specific reference to parameters useful for calculating a sensor pressure for triggering an alarm condition, which are set forth on page 26, line 12-25 and on page 27, lines 1-14. The requested amendment does not introduce any new matter.

Amendment of the paragraph beginning on page 29, line 25 is requested to replace the recitation "specified first-level alarm pressure" with the recitation "configuration specified system pressure." The requested amendment conforms the referenced parameters to the parameters set forth in algorithm provided on page 26 lines 24-25. The requested amendment is supported by the description of exemplary methods of the present invention beginning on page 26, line 14 and ending on page 27, line 8. The requested amendment does not introduce new matter.

Amendments to the Claims

Amendment of claim 6 is requested to change the recitation "specified pressure drop" to recite "specified system pressure." The requested amendment is supported by the description of an exemplary embodiment wherein "the specified system pressure is between about -100 and about -250 mmHg" on page 5 lines 11 and 12. Amended claim 6 does not introduce any new matter.

Amendment of claim 10 is requested to insert "said" before "flow rate." The requested amendment improves antecedent basis and overall clarity. Amended claim 10 does not introduce any new matter.

Amendment of claim 11 is requested to change the recitation "mgHg" to recite "mmHg." The requested amendment corrects an obvious typographical error. Amended claim 11 does not introduce any new matter.

Amendment of claim 16 is requested to change the dependence of the claim from claim 14 to claim 15. The requested amendment improves antecedent basis and overall clarity. Amended claim 16 does not introduce any new matter.

Amendment of claim 24 is requested to change the recitation "specified pressure in the system" to recite "specified system pressure." The requested amendment improves antecedent basis and overall clarity. Amended claim 24 does not introduce any new matter.

Amendment of claim 25 is requested to change the recitation "inlet pump hematocrit, ratio of anticoagulant to whole blood in an inlet line of said system during platelet and plasma collection, inlet pump flow rate, and donor hematocrit" to recite "the hematocrit in the inlet tubing line, the flow rate in the inlet tubing line, the flow rate in the needle, and the hematocrit in the needle." The requested amendment is supported by the description of parameters used in an exemplary algorithm for calculating a sensor

pressure for triggering an alarm condition beginning on page 26, line 12 and ending on page 27, line 14. Amended claim 25 does not introduce any new matter.

Amendment of claim 26 is requested to change the recitation:

> $P_{AAL} = P_{AALS} + 75 - 0.331\ Q_{ININSTD} / (1-H_{IN}) - 0.303\ Q_{ININSTD} (1 - 1/R) / (1 - H) = -350$ where P_{AAL} is the specified sensor pressure that triggers the first-level alarm; P_{AALS} is the specified first-level alarm-triggering system pressure, mmHg; H_{IN} is inlet pump hematocrit, decimal; $Q_{ININSTD}$ is instantaneous inlet pump flow rate (during the draw phase), ml/min; and R is ratio of whole blood to anticoagulant in an inlet line of said system during platelet and plasma collection.

to recite:

> specified sensor pressure = Config + 75 - 0.3309 * $Q_{in}/(1-H_{in})$ - 0.3026 * $Q_n/(1-H_n)$; where Config is a configuration specified system pressure (mmHg.), Q_{in} is the flow rate in the inlet tubing line (ml/min.); H_{in} is the Hematocrit in the inlet tubing line; Q_n is the flow rate in the needle (ml/min.); and H_n is the Hematocrit in the needle.

The requested amendment to claim 26 is supported by the description of an exemplary algorithm useful for calculating a sensor pressure for triggering an alarm condition beginning on page 26, line 12 and ending on page 27, line 14. Amended claim 26 does not introduce any new matter.

Amendment of claim 28 is requested to insert "the" before "pressure of said return flow." The requested amendment improves antecedent basis and overall clarity. Amended claim 28 does not introduce any new matter.

Amendment of claim 30 is requested to change the recitation "return pump flow, return pump hematocrit, return needle flow, and return needle hematocrit" to recite "the flow rate in the inlet tubing line, the hematocrit in the inlet tubing line, the flow rate in the needle, and the hematocrit in the needle." The requested amendment is supported by the description of parameters used in an exemplary algorithm for calculating a sensor

pressure for triggering an alarm condition beginning on page 27, line 24 and ending on page 28, line 11. Amended claim 30 does not introduce any new matter.

Amendment of claim 31 to change the recitation:

> $P_{RAL} = P_{RALS} - 50 - 0.3331\ Q_{ININSTR} / (1 - H_{IN}) - 0.303\ Q_{NRET} / (1 - H_{NRET}) =$ 400where P_{RAL} is the sensor pressure that triggers the return-pressure alarm, mmHg; P_{RALS} is the specified system return-flow alarm-triggering pressure, mmHg, $Q_{ININSTR}$ is return pump flow, ml/min; H_{IN} is return pump hematocrit, decimal; Q_{NRET} is the flow rate through the needle during the single needle return phase, ml/min; and H_{NRET} is the hematocrit of the flow through the return needle.

to recite:

> specified sensor pressure = Config - 50 - 0.3309 * $Q_{in}/(1-H_{in})$ - 0.3026 * $Q_n/(1-H_n)$; where Config is a configuration specified system pressure (mmHg), Q_{in} is the flow rate in the inlet tubing line (ml/min.); H_{in} is the Hematocrit in the inlet tubing line; Q_n is the flow rate in the needle (ml/min.); and H_n is the Hematocrit in the needle.

The requested amendment to claim 31 is supported by the description of an exemplary algorithm useful for calculating a sensor pressure for triggering an alarm condition beginning on page 27, line 24 and ending on page 28, line 11. Amended claim 31 does not introduce any new matter.

Amendment of claim 34 is requested to change the recitation "mgHg" to recite "mmHg." The requested amendment corrects an obvious typographical error. Amended claim 34 does not introduce any new matter.

Amendment of claim 38 is requested to change the recitation "pressure level" to recite "pressure." The requested amendment improves antecedent basis and overall clarity. Amended claim 38 does not introduce any new matter.

Amendment of claim 39 is requested to change the recitation "inlet pump hematocrit, ratio of anticoagulant to whole blood in an inlet line of said system during

platelet and plasma collection, inlet pump flow rate, and donor hematocrit" to recite "the hematocrit in the tubing line, the flow rate in the inlet line, the flow rate in the needle, and the hematocrit in the needle." The requested amendment is supported by the description of parameters used in an exemplary algorithm for calculating a sensor pressure for triggering an alarm condition beginning on page 26, line 12 and ending on page 27, line 14. Amended claim 39 does not introduce any new matter.

Amendment of claim 40 is requested to change the recitation:

> by the following formula: $P_{AAL} = P_{AALS} + 75 - 0.331\ Q_{ININSTD} / (1\text{-}H_{IN}) - 0.303\ Q_{ININSTD}\ (1 - 1/R) / (1 - H) = -350$ where P_{AAL} is the specified sensor pressure; P_{AALS} is the specified system pressure, mmHg; H_{IN} is inlet pump hematocrit, decimal; $Q_{ININSTD}$ is instantaneous inlet pump flow rate, ml/min; and R is ratio of whole blood to anticoagulant in an inlet line of said system during platelet and plasma collection.

to recite:

> $P_{1st\ level\ alarm} = \text{Config} + 75 - 0.3309 * Q_{in}/(1\text{-}H_{in}) - 0.3026 * Q_n/(1\text{-}H_n)$;
>
> wherein $P_{1st\ level\ alarm}$ is the first level alarm-triggering sensor pressure; Config is a configuration specified system pressure (mmHg), Q_{in} is the flow rate in the inlet tubing line (ml/min.); H_{in} is the Hematocrit in the inlet tubing line; Q_n is the flow rate in the needle (ml/min.); and H_n is the Hematocrit in the needle.

The requested amendment to claim 40 is supported by the description of an exemplary algorithm useful for calculating a sensor pressure for triggering an alarm condition beginning on page 26, line 12 and ending on page 27, line 14. Amended claim 40 does not introduce any new matter.

Amendment of claim 41 is requested to change the dependence of the claim from claim 39 to claim 38. The requested amendment is supported by the description of an exemplary embodiment wherein "the specified system pressure is between about

-100 and about -250 mmHg" on page 5, lines 11 and 12. Amended claim 41 does not introduce any new matter.

Amendment of claim 43 is requested to change the dependence of the claim from claim 44 to claim 42. The requested amendment corrects an obvious typographical error and is supported by the description of an exemplary fluid separation control system on page 8, lines 18-24. Amended claim 43 does not introduce any new matter.

Amendment of claim 55 is requested to change the recitation "said said leukocyte reduction chamber" to recite "said leukocyte reduction chamber." The requested amendment corrects an obvious typographical error. Amended claim 55 does not introduce any new matter.

Amendment of claim 65 is requested to change the recitation "mgHg" to recite "mmHg." The requested amendment corrects an obvious typographical error. Amended claim 65 does not introduce any new matter.

New claim 66 has been added to more particularly point out and distinctly claim the present invention. Support for new claim 66 is provided by the description of an exemplary algorithm useful for calculating a sensor pressure for triggering an alarm condition beginning on page 27, lines 15-23. New claim 66 does not introduce any new matter.

New claim 67 has been added to more particularly point out and distinctly claim the present invention. Support for new claim 67 is provided by the description of an exemplary algorithm useful for calculating a sensor pressure for triggering an alarm condition beginning on page 27, line 24 and ending on page 28, line 11. New claim 67 does not introduce any new matter.

New claim 68 has been added to more particularly point out and distinctly claim the present invention. Support for new claim 67 is provided by the description of an exemplary algorithm useful for calculating a sensor pressure for triggering an alarm condition beginning on page 27, lines 15-23. New claim 68 does not introduce any new matter.

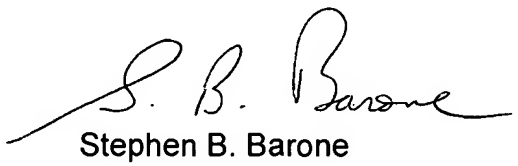
CONCLUSION

In view of the foregoing amendments, this case is considered to be in condition for allowance, and passage to issuance is respectfully requested.

If there are any outstanding issues related to patentability, the courtesy of a telephone call is requested, and the Examiner is invited to call to arrange a mutually convenient time.

It is believed that no additional fee is required with this submission. If this is incorrect, however, please deduct the appropriate fee for this submission and any extension of time required from Deposit Account No. 07-1969.

Respectfully submitted,



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nk: March 18, 2004